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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,934	04/07/2006	Satomi Miyata	MIYATA 6	5550

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EXAMINER	
KUDLA, JOSEPH S	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,934	MIYATA ET AL.	
	Examiner	Art Unit	
	JOSEPH S. KUDLA	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/20/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Applicant's election with traverse of Group V, encompassing instant claims 17-19, in the reply filed on April 4, 2008 is acknowledged. The traversal is on the ground(s) that because only one claim (instant claim 16 (Group IV)) has been found to lack unity, all of the other claims within Groups I-III and V meet unity of invention and should be examined together. This is not found persuasive. Applicant is reminded of PCT Rule 13.2.

PCT Rule 13.2 states:

> Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled **only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.** The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Since Group IV does not share the same special technical feature as Groups I-IV, the claims lack unity.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant's election of Group V, encompassing claims 17-19 and the species 10-hydroxy-2-decenoic acid, in the reply filed on April 4, 2008, is acknowledged. The inventions contained in Groups I-IV, encompassing instant claims 1-16, are withdrawn from consideration as being drawn to non-elected subject matter. See 37 CFR 1.142(b).

Accordingly, the subject matter now under consideration is drawn to claims 17-19.

Priority

3. This application is the U.S. National Phase of International Application PCT/JP04/14591, filed on October 4, 2003 and claims priority to Japanese Foreign Application 2003-348705, filed October 7, 2003. Priority is acknowledged.

Information Disclosure Statement

4. The Information Disclosure Sheet (IDS) correspondence submitted by Applicant on March 20, 2007 is acknowledged and has been reviewed to the extent each is a proper citation on a US Patent and has been supplied.

5. The information disclosure statement filed March 20, 2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specifically, the citation for JP 04-200356 is believed by the Examiner to be incorrect. The IDS incorrectly cites the document as JP 04-200358, but the foreign reference received with the application has the reference numbers JP 04-200356.

Appropriate action is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of

making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. The recitation "and/or" in claim 17 is confusing as to what method is being claimed. *In re Anderegg* 51 USPQ 66.

7. Claims 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

Applicant claims a "derivative" for the fatty acid constituent in instant claims 17-19. Because the instant specification does not provide written description of what structures are contemplated for such "derivatives" for the fatty acid constituent in the instant specification, the phrases lack adequate written description.

Regarding the requirement for adequate written description of chemical entities, Applicants' attention is directed to MPEP § 2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F. 3d 1559, 1568 (Fed. Cir. 1997), *cert denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish list or plan for obtaining the claimed chemical invention." Eli Lilly, 119

F. 3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F. 3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicant has failed to provide any written description for "derivatives" for the fatty acid constituent in the instant specification. As such, it is not apparent that Applicant was actually in possession of, and intended to use, within the context of the present invention, any derivatives for the fatty acid constituent at the time the present invention was made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilmott et al. (US Patent 4,983,382), in view of all Breton et al. (US Patent Application Publication 2002/0012684) and Japanese Publication 10-147514 and provided by Applicant.

Wilmott et al. teach a method of improving the appearance of the skin comprising administering ascorbic acid (Claim 1). Wilmott et al. teach "the essential role played by ascorbic acid in the hydroxylation of proline and lysine, hence the formation and maintenance of collagen has been investigated widely and is well understood" (column 3, lines 1-4).

Wilmott et al. does not teach a method for enhancing collagen with a fatty acid or that the fatty acid can be derived from mineral jelly.

Breton et al. teach 10-hydroxy-2-decenoic acid compounds are well suited for stimulating epidermal renewal and combating extrinsic cutaneous aging (Abstract). Breton et al. teach extrinsic aging causes detrimental clinical changes, such as large wrinkles and the formation of flaccid and weathered skin, and histopathological

changes, such as an excessive accumulation of elastic material in the upper dermis and the degeneration of the collagen fibers (page 1, column 2, paragraph 12). Breton et al. teach a method of combating extrinsic cutaneous aging with administering to an individual subject and effective amount of at least one 10-hydroxy-2-decenoic acid compound (page 3, column 1, paragraph 39).

Japanese Publication 10-147514 teaches 10-hydroxy-2-decenoic acid is an active ingredient of royal jelly (Problem to be solved). The 10-hydroxy-2-decenoic acid compound can be between 0.001 and 10% (Solution).

It would have been obvious to one of ordinary skill in the art at the time of the invention that since Wilmott et al. teach a method of improving the formation and maintenance of collagen comprising administering ascorbic acid and Breton et al. teach a method of combating extrinsic cutaneous aging (*i.e.*, through stimulating epidermal renewal and slowing the degeneration of the collagen fibers) comprising administering an effective amount of at least one 10-hydroxy-2-decenoic acid compound, that a method utilizing a pharmaceutical composition combining the two would similarly be useful in enhancing collagen production and would render claims 17 and 19 obvious. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to

be *prima facie* obvious.).

It would have been obvious to one of ordinary skill in the art at the time of the invention that in view of Japanese Publication 10-147514, 10-hydroxy-2-decenoic acid is able to be purified from royal jelly, thus rendering instant claim 18 obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937,214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Application 10/491,138

9. Claims 17-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 10/491,138. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 12 of the co-pending application is directed to a method of enhancing TGF-β production, enhancing collagen production, comprising administering L-ascorbic acid and/or its derivative and royal jelly. In addition, because it is known that one of the active components of royal jelly is 10-hydroxy-2-decenoic acid (see Japanese Publication 10-147514 reference), then a composition comprising administering royal jelly will inherently administer 10-hydroxy-2-decenoic acid as well, thus rendering instant claims 17-19 obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-

3288. The examiner can normally be reached on 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph S. Kudla/
Examiner, Art Unit 1611
June 27, 2008

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615